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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/469,200 | 12/21/1999 | PAUL H. WEIGEL | 5820.555 | 4696 |

36589 7590 10/20/2003

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/469,200 | WEIGEL ET AL. | |
| | Examiner | Art Unit | |
| | Gabriele E. BUGAISKY | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 51-59 is/are pending in the application.
- 4a) Of the above claim(s) is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 10, and 51-59 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>703</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The specification is not in comppliance with 37 C.F.R. 1.821-1.825, as not all sequences are identified by their SEQ ID NO: (e.g., page 80, lines 13-17 of the 12/10/2001 specification).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants have presented no information that the HAS gene is a palindrome; unless such is the case, the claimed invention cannot both encode the enzyme AND hybridize to SEQ ID NO. 1, which is the coding sequence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 10 and 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 3 and 51-59, it is not clear what is intended by the phrase “in accordance with SEQ ID NO:x” or “according to SEQ ID NO:x. Does it mean that the nucleotide sequence has the exact sequence of SEQ ID NO:x, or is another meaning implied? The term is especially confusing for claims 55-58-it cannot be determined whether the claimed sequences comprise or consist of the recited SEQ ID NOS,

Claim 51, line 5 recites “encoding for”. The proper terms would be either “encoding” or “coding for”.

Further, claim 59, (a) recites the nucleic acid segment according to SEQ ID NO:2- SEQ ID NO:2 is a protein sequence and not a nucleic acid sequence. Part (c) and d) are totally unclear-the limitation of the preamble states the nucleic acid has encodes enzymatically active HAS, but parts c and d)) states the nucleic acid hybridize to the coding region, and c) also recites fragments. Is one to imply the coding strand is palindromic and are only fragments encoding enzymatically active HAS what is intended by this portion of the claim?

Claim 10 depends from now canceled claim 9, and is therefore indefinite.

Claim 52 is included in this rejection as it depends from claim 51 and does not clarify the ambiguity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 10, 51-54 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by WO94 00463 (Prehm *et al.*; reference G on the IDS of 7/2003). The reference is anticipatory for the claimed subject matter because it provides recombinant bacterial cells transformed with a *S. equisimilis* hyaluron synthase gene, and a recombinant method of producing the enzyme. With respect to claims 4 and 59, it is deemed that under non-defined hybridization conditions, any gene would hybridize to SEQ ID NO:1. With respect to claim 5, with the reference is deemed anticipatory because the term "has" is open language and does not limit the number of substitutions, additions and deletions which would allow one to derive SEQ ID NO:1 from the DNA of the reference. With respect to claim 51, the reference is deemed anticipatory because the disclosed DNA has the recited biological property. .

Claims 1, 4-5, 54 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by. ITANO *et al.*. The reference is anticipatory for the claimed subject matter because it provides recombinant cells transformed with a *Mus* hyaluron synthase gene, and a recombinant method of producing the enzyme. With respect to claims 4 and 59, it is deemed that under non-defined hybridization conditions, any HAS gene would hybridize to SEQ ID NO:1. With respect to claim 5, with the reference is deemed anticipatory because the term "has" is open

language and does not limit the number of substitutions, additions and deletions which would allow one to derive SEQ ID NO:1 from the DNA of the reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 54 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6455304. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a species of nucleic acids encoding hyaluronate synthase, whereas the instant claims are generic. A species renders a genus obvious.

Conclusion

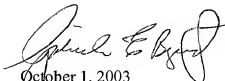
Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on Tu & Th 8:15 AM- 2 PM; We. & Fr 8:15 AM- 1:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653



October 1, 2003